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3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION

Musculoskeletal Transplant Foundation
125 May Street
Edison, NJ 08837
Tel: 732-661-0202
http://www.mtf.org

B. ESTABLISHMENT REGISTRATION NUMBER: 2249062

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, MD 20854
estrin@yourfdaconsultant.com

Tel: (301) 279-2899
Fax: (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: December 21, 2004

E. PROPRIETARY (TRADE) NAME: **MTF™ Allograft Anchor**

F. COMMON NAME: Bone anchor

G. CLASSIFICATION NAME:
Nonabsorbable Poly(ethylene Terepthalate) Surgical Suture

H. REGULATION NUMBER: 21 CFR 878.5000

I. PROPOSED REGULATORY CLASS: Class II

J. DEVICE PRODUCT CODE: GAT

K. PANEL CODE : 87 OR Orthopedic

L. DESCRIPTION OF DEVICE

The anchor, suture, needles and inserter are all packaged together. The kit contains one allograft anchor, loaded with one strand of #2 braided polyester suture, green, and one strand of #2 braided polyester suture, white. To each end of suture is attached a CP-2 needle. The anchor, suture and needles are housed in an inserter. The anchor resides at the tip of the tube while the bulk of the suture and the needles reside in the card placed within the inserter handle.

The inserter, with the enclosed anchor, et al., delivers the product to the site. The inserter is composed of a plastic body (with an anchor release mechanism) and a stainless steel tube with a stainless steel shaft for anchor deployment. A drill or punch is provided to create a hole to deliver the anchor. The inserter, contents are housed within a plastic tray. All components are single use only and sterile.

M. INDICATIONS FOR USE

The Allograft Anchor is intended for use in soft tissue approximation and/or ligation in orthopaedic procedures.

N. PREDICATE DEVICE

The **MTF™ Allograft Anchor** is substantially equivalent to The Phoenix™ 5.0 Allograft Anchor Kit (K011985), manufactured by Smith and Nephew.

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Both the **MTF™ Allograft Anchor** and The Phoenix 5.0 Allograft Anchor Kit have the same indications for use. **MTF™ Allograft Anchor** and its predicate are both made from machined human allograft bone derived from the tibia or femur recovered from deceased donors. Both **MTF™ Allograft Anchor** and its predicate require implantation into bone through use of an attached insertion device. The Smith and Nephew and **MTF™ Allograft Anchor** use USP Size Number 2 Braided Polyester Sutures.

P. SUMMARY OF STUDIES

Biomechanical testing of the **MTF™ Allograft Anchor** was performed to investigate whether the anchor meets design requirements. The conclusion of the anchor insertion and fixation test confirmed that the **MTF™ Allograft Anchor** meets design input requirements for strength. The tests also confirmed that the **MTF™ Allograft Anchor** dimensions were within design requirements. Insertion repeatability was found to be acceptable and pullout values for fixation strength exceeded those of metal and polymeric devices used for similar types of fixation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2004

Musculoskeletal Transplant Foundation
c/o Mr. Norman F. Estrin, Ph.D., RAC
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K042038
Trade/Device Name: Allograft Anchor
Regulation Number: 21 CFR 878.5000
Regulation Name: Synthetic non-absorbable PET suture
Regulatory Class: II
Product Code: GAT
Dated: December 1, 2004
Received: December 6, 2004

Dear Dr. Estrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042038

Device Name: Allograft Anchor

Indications for Use:

The Allograft Anchor is intended for use in soft tissue approximation and/or ligation in orthopaedic procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042038